

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Children's Nappy Rash Cream or Infant Nappy Rash Cream

Boots Antiseptic Nappy Rash Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients	% w/w
Cetrimide Ph Eur	0.5
Dimethicone 20 Ph Eur	10.0

3 PHARMACEUTICAL FORM

Cream

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment and prevention of nappy rash.

4.2 Posology and method of administration

For topical application to the skin.

Use during each nappy change.

Clean and thoroughly towel dry the nappy area.

Spread the cream lightly and evenly over the whole nappy area and then rub gently into the skin.

4.3 Contraindications

Hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Do not use if the skin is weeping or badly inflamed.

Avoid contact with the eyes.

For external use only.

Keep all medicines out of the reach of children.

Instruct patients not to smoke or go near naked flames – risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

4.5 Interaction with other medicinal products and other forms of interaction

There are no clinically significant interactions

4.6 Fertility, pregnancy and lactation

The safety of this product during pregnancy and lactation has not been established but is not considered to constitute a hazard during these periods.

4.7 Effects on ability to drive and use machines

No adverse effects known.

4.8 Undesirable effects

Skin irritation may occasionally occur and hypersensitivity reactions may develop in certain individuals.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

It is unlikely that systemic toxicity will result from the ingestion of Children's Nappy Rash Cream although it may give rise to gastrointestinal irritation and possibly laxation

Treatment should be symptomatic.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Dimethicone 20 is water repellent and will protect the skin against water soluble irritants. Cetrimide is a quaternary ammonium disinfectant having bactericidal activity against both gram-positive and gram-negative organisms.

5.2 Pharmacokinetic properties

None stated.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorocresol
Liquid paraffin
Cetostearyl alcohol
Zinc oxide
Perfume compound DROM 442996
Purified water.

6.2 Incompatibilities

None stated.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store below 25⁰C.

6.5 Nature and contents of container

A polypropylene tub fitted with a polypropylene cap or a green or white polyethylene cap.

Pack size: 125gm or 300gm

6.6 Special precautions for disposal

None stated.

7 MARKETING AUTHORISATION HOLDER

The Boots Company PLC
1 Thane Road West

Nottingham NG2 3AA

8 MARKETING AUTHORISATION NUMBER(S)

PL00014/5260R

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

25 July 1989 / 24 January 1995

10 DATE OF REVISION OF THE TEXT

13/09/2019